



Designated Record Set # 1660.110

INITIAL EFFECTIVE DATE:	LAST REVISION DATE:	RESPONSIBLE UNIVERSITY DIVISION/DEPARTMENT
August 31, 2021	August 31, 2021	Office of Compliance and Integrity

POLICY STATEMENT

Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and Florida law, patients have access to, may request copies of, and may request amendments of their protected health information (PHI) in their Designated Record Set (DRS). Florida International University (FIU) HIPAA Hybrid Designated Health Care Components (Components) must specifically define, maintain and allow a patient who is the subject of the Protected Health Information (PHI) or their legal representative (FIU Policy and Procedure #1660.001) (Representatives) certain rights to a DRS per the procedure outlined below. The DRS will encompass information beyond the traditional medical record and billing record. Healthcare providers must include information received from another health care provider during the patient’s visit in their DRS unless the health care provider has documented facts that the information was not used in whole or in part to make a decision about the patient.

As a University-wide policy and procedure, this policy and procedure takes precedence over any Component-specific policies, procedures, or protocols that conflicts with this policy and procedure, unless prior approval is obtained from the Office of Compliance and Integrity. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

Components may maintain HIPAA documentation in either paper or electronic form, provided that any format is sufficiently protected to ensure it will be retrievable throughout the required retention period. Unless otherwise indicated in FIU Privacy or Security Rule Policy and Procedure, each Component Privacy Coordinator will be responsible for maintaining all HIPAA documentation relevant to his/her Component. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

All Component Workforce members shall receive mandatory HIPAA Privacy and Security Rule training. (FIU Policy and Procedure #1660.075) (HIPAA Privacy and Security Rule Training)

Component Workforce members who fail to adhere to this policy and procedure may be subject to civil and criminal penalties as provided by law, and/or administrative and disciplinary action. (FIU Policy and Procedure #1660.085) (Sanctions)



Each Component must designate a HIPAA Privacy Coordinator and a HIPAA Security Coordinator. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

FIU reserves the right to amend, change or terminate this policy and procedure at any time, either prospectively or retroactively, without notice. Any ambiguities between this policy and procedure and the other policies and procedures should be harmonized consistent with the requirements of HIPAA, federal and state law and regulation. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

SCOPE

This policy applies to FIU's health care providers/Components that are contained within FIU's HIPAA Hybrid Designation (FIU Policy and Procedure #1610.005), its Workforce members and Business Associates as defined in the policy and FIU Policy and Procedure #1660.015 regarding Business Associate Agreements.

REASON FOR POLICY

The reason for this policy and procedure is to address what constitutes a Designated Record Set and to provide guidance regarding the creation and maintenance of Designated Record Sets as required by HIPAA and Florida law.

45 CFR §164.501
F.S. §456.057

DEFINITIONS

TERM	DEFINITIONS
Access	Means the ability or means necessary to read, write, modify, or communicate data/information or otherwise use and system resource.
Administrative Officer	Means the Component Workforce member responsible for financial management, human resources administration, management of facilities and equipment, and other administrative functions required to support the teaching and research missions of the FIU HIPAA Hybrid Designated Health Care Component. The Administrative Officer is the senior administrative staff position in the department, Division or Office and provides continuity as academic leadership changes.



Availability	Means the property that data or information is accessible and useable upon demand by an authorized person.
Business Associate	<p>Generally, an entity or person who performs a function involving the use or disclosure of PHI on behalf of a covered entity (such as claims processing, case management, utilization review, quality assurance, billing) or provides services for a covered entity that require the disclosure of PHI (such as legal, actuarial, accounting, accreditation).</p> <p>NOTE: A business associate relationship exists when an individual or entity, acting on behalf of an FIU HIPAA Component(s), assists in the performance of a function or activity involving the creation, use, disclosure, or access of PHI. This includes, but not limited to, claims processing or administration, data analysis, utilization review, quality assurance, billing, benefit management or repricing.</p> <p>NOTE: A Business Associate may include any individual or entity that receives PHI from a HIPAA Component in the course of providing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, software support, or financial services. A Business Associates does not, however, include HIPAA Component workforce members.</p>
Code of Federal Regulations	Also known as CFR is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation.
Component	Means a component or combination of components of a hybrid entity designated by the hybrid entity (Florida International University). Those programs designated by FIU that must comply with the requirements of the Health Insurance Portability and Accountability Act of 1996, hereinafter referred to as "Components". Components of FIU are required to comply with the Administrative Simplification provisions of HIPAA because the Components perform a covered function.
Covered Entity	An entity that is subject to HIPAA. <ul style="list-style-type: none"> 1. a health plan; 2. a health care clearinghouse; and/or

	3. a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.
Designated Record Set	<p>1. A group of records maintained by or for a covered entity that is:</p> <ul style="list-style-type: none"> a. The medical records and billing records about patients maintained by or for a covered health care provider; b. The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or c. Used, in whole or in part, by or for the covered entity to make decisions about patients. <p>2. For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a covered entity.</p>
Disclosure	Means the release, transfer, provision of access to, or divulging in any other manner of PHI outside of the entity holding the information.
Electronic Protected Health Information (ePHI)	PHI in electronic form. See also: <u>PHI</u> .
Florida Statutes	Also known as F.S. is a permanent collection of state laws organized by subject area into a code made up of titles, chapters, parts, and sections. The Florida Statutes are updated annually by laws that create, amend, transfer, or repeal statutory material.
Health Care	Means the care, services, or supplies related to the health of a patient, including: <ul style="list-style-type: none"> 1. preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of a patient or that affects the structure or function of the body; and 2. sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.
Health Care Component	See "Component"
Health Care Provider	Means a provider of medical or health services and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.
Health Information	Means any information, whether oral or recorded in any form or medium, that is created or received by a health care provider,



	health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an patient; the provision of health care to an patient; or the past, present, or future payment for the provision of health care to an patient.
U.S. Department of Health and Human Services	Also known as HHS.
HIPAA	Means the Health Insurance Portability and Accountability Act of 1996.
Hybrid Covered Entity	Means a single legal entity that performs both covered and non-covered functions. The entity has a defined health care component that engages in HIPAA electronic transactions.
Minimum Necessary	Means the limit use, disclosure, or request of PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.
Patient	The person who is the subject of the PHI
Permitted	Means health care providers <u>may</u> , but are not required to, use or disclose patient PHI without authorization for its own treatment, payment, or healthcare operations (except for marketing purposes), and, in most cases, for treatment, payment and healthcare operations of other covered entities.
Person	Means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.
Privacy Coordinator	Means an FIU Workforce member, appointed by the director, manager, or supervisor of a HIPAA Designated Component to conduct and/or coordinate with necessary and appropriate Workforce members all HIPAA Privacy Rule activities and actions within the Component, including but not limited to tracking HIPAA training activities; coordinating HIPAA Privacy Rule implementation; participating in HIPAA Privacy and Security Rule violation investigations, as necessary and appropriate, communicating with the Director of Compliance and Privacy for Health Affairs, the HIPAA Security Officer, and the Office of General Counsel, as necessary and appropriate, regarding HIPAA Privacy and Security Rule activities and concerns; conducting and reporting monitoring activities; participate in assessments; and responding to, tracking and documenting HIPAA Privacy Rule activities. Maintain ongoing communication with the Director of



	Compliance and Privacy for Health Affairs and the HIPAA Security Officer.
Protected Health Information	Means any individually identifiable health information collected or created in the course of the provision of health care services by a covered entity, in any form (written, verbal or electronic). PHI relates to the past, present, or future physical or mental health or condition of an individual or the past, present, or future payment for the provision of health care to an individual. PHI, however, specifically excludes: <ol style="list-style-type: none"> 1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g (“FERPA”); 2. Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and 3. Employment records held by a covered entity in its role as an employer.
Record	Any item, collection, or grouping of information that includes PHI and is maintained, collected, used, or disseminated by or for a Health Care Provider/Component
Treatment	Means the provision, coordination, or management of health care and related services among health care providers or by a healthcare provider with a third party, or consultative services among providers regarding a patient.
Use	With respect to patient identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.
Workforce	Means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity (FIU HIPAA Component) or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

ROLES AND RESPONSIBILITIES

1. **Compliance Oversight: The Office of University Compliance and Integrity (University Compliance)**
 - Evaluates all federal and state healthcare privacy laws, regulations, rules and ordinances (Rules) to ensure compliance with the Rules
 - Develops and maintains all required University-wide Privacy Rule policies and procedures.

- Develops and maintains HIPAA health care Privacy Rule training modules and ensures appropriate Workforce members complete the required training.
- Performs audits and assessments of the Components to ensure their compliance with the Privacy Rules and associated FIU Policies and Procedures.
- Assist and provide guidance as necessary and appropriate to establish and maintain patient DRSs.
- Partners with the Division of Information Technology HIPAA Security Officer to ensure compliance with all federal and state healthcare privacy and security laws, regulations rules, and ordinances.

2. HIPAA Components:

- Each Component must designate a Privacy Coordinator responsible for overseeing and ensuring the Component's implementation and compliance with the HIPAA Privacy Rule, FIU's associated HIPAA Privacy Policies and Procedures, and any applicable state laws and/or regulations governing the confidentiality, integrity and availability of PHI and ePHI.
- Creating and maintaining DRSs.

3. Compliance Oversight: The Division of Information Technology

- Evaluates all federal and state healthcare privacy laws, regulations, rules and ordinances (Rules) to ensure compliance with the Rules.
- Develops and maintains all required University-wide Security Rule policies and procedures.
- Develops and maintains HIPAA health care Security Rule training modules and ensures appropriate Workforce members complete the required training.
- Performs audits and assessments of the Components to ensure their compliance with the Security Rules and associated FIU Policies and Procedures.
- Partners with the Office of Compliance and Integrity Director of Compliance and Privacy for Health Affairs to ensure compliance with all federal and state healthcare privacy and security laws, regulations rules, and ordinances.

RELATED RESOURCES

References

- 45 CFR §164.501
- 45 CFR §164.502
- 45 CFR §164.504
- 45 CFR §164.524
- 45 CFR §164.526
- F.S. §95.11
- F.S. §456.057

Related Policies

- FIU Policy and Procedure # 1610.005 (Designated Health Care Components of FIU Community)
- FIU Policy and Procedure #1660.001 (Representatives)
- FIU Policy and Procedure #1660.015 (Business Associate Agreements)
- FIU Policy and Procedure #1660.045 (Right of Patients to Request Restrictions Regarding the Use and Disclosure of Their Protected Health Information)
- FIU Policy and Procedure #1660.050 (Patient Access to Protected Health Information)
- FIU Policy and Procedure #1660.055 (Amendment of Protected Health Information)
- FIU Policy and Procedure #1660.070 (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)
- FIU Policy and Procedure #1660.075 (HIPAA Privacy and Security Rule Training)
- FIU Policy and Procedure #1660.080 (Policies and Procedures, Changes to Policies and Procedures, and Documentation)
- FIU Policy and Procedure #1660.085 (Sanctions)

CONTACTS

For further information concerning this policy, please contact the FIU Office of Compliance & Integrity at (305) 348-2216, compliance@fiu.edu, or the appropriate Component Privacy Coordinator.

HISTORY

Initial Effective Date: August 31, 2021

Review Dates (*review performed, no updates*): N/A

Revision Dates (*updates made to document*): August 31, 2021



Designated Record Set # 1660.110a

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PROCEDURE STATEMENT

I. Creation and Maintenance of Patient Designated Record Sets (DRS)

Each Florida International University (FIU) Health Insurance Portability and Accountability Act (HIPAA) Hybrid Designated Healthcare Component (Component) must designate a Privacy Coordinator responsible for overseeing and ensuring the Components implementation and compliance with the HIPAA Privacy Rule, FIU’s associated HIPAA Privacy Policies and Procedures, and any applicable federal and state laws and regulations governing the confidentiality, integrity and availability of patient Protected Health Information (PHI) and electronic PHI (ePHI), including, but not limited to, specifying in writing which forms and reports, when present in a patient’s paper or electronic file, will be included in the Designated Record Set (DRS) based on the HIPAA definition of a DRS. Privacy Coordinators may delegate and share duties and responsibilities as necessary and appropriate but retain oversight responsibility. (FIU Policy and Procedure #1660.070) (Designation of HIPAA Privacy Officer and Component Privacy and Security Coordinators)

Each Healthcare Component must at a minimum, include the following forms and reports in the Component’s DRS. (See Attachment A)

II. Record Retention

- A. If a communication, action, activity, or designation is required to be documented in writing, the document or record owner will maintain such writings, or an electronic copy, for seven (7) years from the date of its creation or the last effective date, whichever is later. (FIU Policy and Procedure #1660.080) (Policies and Procedures, Changes to Policies and Procedures, and Documentation)

III. Forms

- Attachment A (Examples of items that make-up a DRS)

Attachment A (Example of items that make-up a DRS)

<u>INCLUDES</u>	EXAMPLES
Medical Practice (Clinical)	<ul style="list-style-type: none"> • Advanced Directives • Allied Health Reports (OT/PT, Speech Therapy, Nutrition, etc.) • Anesthesia records • Authorization forms • Cardiology reports • Care plans • Consent forms (i.e., Informed Consent and General Consent for Treatment) • Consultation reports • Copies from physician offices or other healthcare facilities used to make health care decisions, such as a history and physical examination or surgical records • Correspondence (i.e., referral letters, record requests, etc.) • Discharge reports (i.e., summary, progress note, instructions) • Documentation of miscellaneous services, including social service, case management, food and nutrition, physical therapy, speech therapy, occupational therapy, respiratory treatments, arterial blood gas reports, and ventilator sheets • Documented communications between provider and patient • Face-sheet • History and Physical Examination Report or Prenatal Record • Informed consent forms for items such as surgery, blood, and dialysis • Interdisciplinary education record • Immunization records • Laboratory Reports/Results, including blood typing or crossmatching (not requisitions for lab tests) • Medication Administration Records • Nursing documentation, including items such as vital sign graphics, intake and output records, neurocheck, medication sheets, intravenous fluid flow sheets, shift assessments,

	<p>nursing notes, telemetry, admission history, care plan, discharge instructions, and release of body form.</p> <ul style="list-style-type: none"> • Operative/Procedure records • Order or prescription for a test/treatment • Other Diagnostic Reports (i.e., EEG, EKG, EMG, NCV, Echo, etc.) • Pathology reports • Patient education records/discharge instructions • Peri-operative documentation, including items such as surgery checklist, anesthesia records, intraoperative nursing forms, and recovery room forms • Problem list • Progress notes (including medical student notes that are co-signed by the supervising physician (with or without an addendum)) • Provider Orders • Imaging/Radiology reports • Registration Record • Selected photographs • Transfer Records • Transport Records
<p>Billing Records</p>	<ul style="list-style-type: none"> • Coding summary • Complete statement of account containing billing history • Open balance statement • Receipt for service (per encounter date) • Financial agreement w/private patients • Requests/Denials for amendments/corrections • Financial payment arrangement • Encounter forms • Paper claims • Other Patient specific claims, remittance, eligibility response and claim status response, charge screen, statement of account balance, payment agreement
<p>Business Associate Records</p>	<ul style="list-style-type: none"> • Records held by a Business Associate that meet the definition of DRS.
<p><u>DRS DOES NOT INCLUDE</u></p>	<p>EXAMPLES</p>

<p>Source Documentation</p>	<p>The following information is usually considered part of the source data of the DRS. In most cases, patients cannot interpret source data, so such data is meaningless. There may be times, however, when a patient has a legitimate need to access source data. When such a need arises, the health care component Unit will want to provide the patient with greater rights of access, allowing the patient access to or copies of the source data when possible. A specific request, authorization or subpoena is required to produce the original or to obtain a copy (if retained and/or able to copy) of this information:</p> <ul style="list-style-type: none"> • Endoscopy photographs • Photographs that taken in the operation/emergency room and are not maintained as part of the medical record. • All release of information related correspondence (e.g., requests for copies from insurance companies, authorization forms, interdepartmental requests for records, and fax cover sheets) <u>as long as the documents are not maintained in the EMR</u> • Psychotherapy Notes as defined by the Standards for Privacy of Individually Identifiable Health Information (§164.501) • Peer review information • Incident reports • Infection control reports • Administrative, attorney-client privileged and any other protected reports • Medical student notes not co-signed by the supervising physician • Temporary notes or worksheets, reminders, and concurrent coding worksheets • Incomplete record coversheets, • clarification notes to/from physicians, etc.
<p>Related to Risk Management, Quality Improvement</p>	<ul style="list-style-type: none"> • Quality Improvement/Peer review records • Risk Management records • Information compiled in reasonable anticipation of, or for use in civil, criminal, or administrative action or proceeding (e.g., Incident Reports- used to identify problems and implement corrective action, attorney notes)

Employment Related	<ul style="list-style-type: none"> • Results of HIV tests maintained by the employee health nurse for employees who incur needle stick injuries while at work • Employer records
Student Health Records	<ul style="list-style-type: none"> • Student education records (e.g., records protected under the Family Educational Rights and Privacy Act (“FERPA”))
Health Information Generated, Collected, or Maintained for Purposes that do not include decision-making about the patient.	<ul style="list-style-type: none"> • Birth and Death Registers • Cancer Registry • Trauma Registry • Diagnostic or Operative Indexes • Copies of reports/documentation/forms, i.e. “shadow files”, wherein the originals are maintained in an 'official' record maintained by the healthcare Component. • Appointment and surgery schedules
Laboratory/Clinical	<ul style="list-style-type: none"> • Administrative records created or maintained by FIU administrative personnel and offices/units that perform support functions on behalf of other Health Care Components as defined in FIU Policy and Procedure #1610.005 (Designated Health Care Components of FIU Community)
Business Associates	Business associate records that meet the definition of DRS but are merely duplicate information maintained by the organization, e.g., dictated notes
Research	Data collected and maintained for research
External/Outside Medical Records	Medical records created by treating entities or providers other than the FIU Unit that have not been used to make a decision about the patient.